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Steven Johnson, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for C.I. Pigments Violet 19, Red 122, and Dihydro Quinacridone

Dear Administrator Johnson:

The following comments on the Color Pigment Manufacturers Association (CPMA) test plan for C.I. Pigments Violet 19, Red 122, and Dihydro Quinacridone are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

CPMA submitted its test plan in June 2006 for the chemicals C.I. Pigment Violet 19 (Violet 19) (CAS RN 1047-16-1), C.I. Pigment Red 122 (Red 122) (CAS RN 980-26-7), and Dihydro Quinacridone (DHQ) (CAS RN 5862-38-4). According to the test plan, the Quinacridones are structurally-related pigments used in the production of industrial finishes and weather resistant paints. CPMA has grouped the three pigments into a category for purposes of the HPV challenge program, and is using available data for all three pigments to complete its sponsorship of these chemicals.

We support this thoughtful toxicology approach. We do however have a few suggestions that could improve the test plan.

Often in order to show the extent of similarity of category chemicals, sponsors may construct a table comparing the known properties of the test chemical and any analogs. CPMA has started to do this on page 5 of the test plan, but perhaps an organized table, with more physicochemical and/or toxicity data, if available, would be helpful in determining the similarities of the three chemicals. Even modeled data for each property and chemical would help.

According to the test plan, ADME studies show that the pigments are not absorbed in any appreciable amounts through the GI tract. Given this, the available data and submitted test plan are more than adequate to fulfill the screening-level HPV program. However, it would be helpful

to more clearly state the available evidence of the pigments' absorption characteristics, and also to more clearly state the evidence available which lead the sponsors to conclude that the reproductive and developmental endpoints are fulfilled. For example, many sponsors can use analyses of reproductive organs or endpoints conducted during a repeated-dose study to fulfill the reproductive toxicity requirement. Here it appears that this might be possible. Additionally, a search of the Hazardous Substances Databank (HSDB), available through ToxLine, reveals two additional studies indicating that Violet 19 is not soluble in water or other solvents. These studies might help to more clearly indicate how the sponsors have fulfilled the HPV program endpoints.

This test plan is an example of the thoughtful toxicology that is needed to be consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to the HPV program. Thank you for your attention to these comments. We may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org with any further questions.

Sincerely,

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Research Analyst

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Director of Research